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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,480	09/18/2003	Thomas C. Boone	A-827	2075

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,480

Applicant(s)

BOONE ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-163 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-163 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16, drawn to peptides and compositions containing the same, classified in class 514, subclass 12.
 - II. Claims 17-22, drawn to polynucleotides encoding the peptides of Group I, and expression vectors and host cells comprising the same, classified in class 536, subclass 23.1.
 - III. Claims 23-38, drawn to peptides and compositions containing the same, classified in class 514, subclass 12.
 - IV. Claims 39-44, drawn to polynucleotides encoding the peptides of Group III, and expression vectors and host cells comprising the same, classified in class 536, subclass 23.1.
 - V. Claims 45 and 46, drawn to peptides, classified in class 530, subclasses 326 and 327.
 - VI. Claims 47-58, 156, 157, 160, and 161, and claims 134-138 (as they depend from claims 156, 157, 160, and 161), drawn to peptides and compositions containing the same and their therapeutic methods of use, classified in class 514, subclass 12.
 - VII. Claims 59-64, drawn to polynucleotides encoding the peptides of Group V, and expression vectors and host cells comprising the same, classified in class 536, subclass 23.1.
 - VIII. Claims 65, 66, and 68-79, drawn to peptides and compositions containing the same, classified in class 514, subclass 12.
 - IX. Claims 67, drawn to peptides, classified in class 530, subclasses 324 and 326.

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- X. Claims 80-85, drawn to polynucleotides encoding the peptides of Group VIII, and expression vectors and host cells comprising the same, classified in class 536, subclass 23.1.
- XI. Claims 86, 87, 89-100, 158, 159, 162, and 163, and claims 134-138 (as they depend from claims 158, 159, 162, and 163), drawn to peptides and compositions containing the same and their therapeutic methods of use, classified in class 514, subclass 12.
- XII. Claim 88, drawn to peptides, classified in class 530, subclasses 324 and 326.
- XIII. Claims 101-106, drawn to polynucleotides encoding the peptides of Group XI, and expression vectors and host cells comprising the same, classified in class 536, subclass 23.1.
- XIV. Claims 107, 108, 110, 112, and 114-125, and claims 134-138 (as they depend from claims 124 and 125), drawn to peptides and compositions containing the same and their therapeutic methods of use, classified in class 514, subclass 12.
- XV. Claims 109, 111, and 113, drawn to peptides and compositions containing the same, classified in class 514, subclass 12.
- XVI. Claims 126-131, drawn to polynucleotides encoding the peptides of Group XV, and expression vectors and host cells comprising the same, classified in class 536, subclass 23.1.
- XVII. Claims 132 and 133, drawn to a composition of matter comprising a peptide, classified in class 530, subclass 324.

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XVIII. Claims 139-149, drawn to peptides and compositions containing the same, classified in class 514, subclass 12.

XIX. Claims 150-155, drawn to polynucleotides encoding the peptides of Group XVIII, and expression vectors and host cells comprising the same, classified in class 536, subclass 23.1.

The inventions of Groups I-XIX are patentably distinct from each other because of their materially different structures and their materially different methods of use. Peptides comprised of amino acids are materially different from polynucleotides comprised of nucleic acids. The peptides as claimed can be used therapeutically, whereas the polynucleotides as claimed can be used to synthesize the peptides. The peptides of Groups I, III, V, VI, VIII, IX, XI, XII, XIV, XV, XVII, and XVIII are patentably distinct from each other because of their materially different amino acid sequences. The polynucleotides of Groups II, IV, VII, X, XIII, XVI, and XIX are patentably distinct from one another because of their materially different nucleotide sequences. Search of each of the groups of claims would require different sequence searches, and thus constitutes an undue burden upon the examiner.

2. If Applicants elect the invention of Group III, the following sequence restriction is imposed:

Claims 23, 24, 27-31, and 34-38 are generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:277 and 278. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required

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under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed. Generic claims 23, 24, 27-31, 34, 36, and 37 will be examined with the elected sequence.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

3. If Applicants elect the invention of Group VI, the following sequence restriction is imposed:

Claims 47-58, 156, 157, 160, and 161 are generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:208, 209, 224, 233, 234, 241, 246, 279, and 280. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

4. If Applicants elect the invention of Group IX, the following sequence restriction is imposed:

Claim 67 is generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:203, 228, 240, 247, and 266. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

5. If Applicants elect the invention of Group XII, the following sequence restriction is imposed:

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Claim 88 is generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:210, 230, 232, 236, 239, and 251. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

6. If Applicants elect the invention of Group XV, the following sequence restriction is imposed:

Claims 109, 111, and 113 are generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:202, 211, 219, 221, 231, 237, and 272. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed. Should applicant traverse on the ground that the sequences

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are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

7. If Applicants elect the invention of Group XVI, the following sequence restriction is imposed:

Claims 126-131 are generic to a plurality of disclosed patentably distinct sequences comprising polynucleotides which encode SEQ ID NOS:202, 211, 219, 221, 231, 237, and 272. These sequences are patentably distinct, each from the other, because of their materially different nucleotide sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed. Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

8. If Applicants elect the invention of Group XVII, the following sequence restriction is imposed:

Claims 132 and 133 are generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:1-58 and 202-280. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

9. If Applicants elect the invention of Group XVIII, the following sequence restriction is imposed:

Claims 139-149 are generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:8, 10, 23, and 24. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the

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claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

10. If Applicants elect the invention of Group XIX, the following sequence restriction is imposed:

Claims 150-155 are generic to a plurality of disclosed patentably distinct sequences comprising polynucleotides which encode SEQ ID NOS:8, 10, 23, and 24. These sequences are patentably distinct, each from the other, because of their materially different nucleotide sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed. Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior

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art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

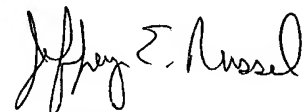
This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
November 8, 2004